State of Utah

Department of Commerce

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Division of Occupational and Professional Licensing

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REMOTE DISPENSING **PHARMACY**

INSPECTION

Investigation Fax: (801) 530-6301 New Opening ☐ Random

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685 - 155 a.		Personnel		
	interns, pharmacy technicia	ns and techs-in-trainin	g (attach a separate sheet, i	f necessary):
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		, and A	CLASS A PHARMACY CLASS B PHARMACY
1	YES	NO	The facility shall maintain a current list of licensed employees involved in the practice of the pharmacy at the facility. The list shall include individual licensee names, license classifications, license numbers, and license expiration dates. The list shall be readily retrievable. The list may
			be maintained in paper or electronic form. [UAC R156-17b-614a (5)]
2	er Las e Van		Notification has been provided to the Division in regards to the unique email address used for self audits or pharmacy alerts. The pharmacy will notify the division of any change in the email address within seven days of the change. [UAC R156-17b-603 (2) and (3) (t) (i-ii)]
3			Notification has been provided to the Division in regards to the assignment of the RDPIC at the above stated pharmacy. The Division is notified of a change in RDPIC within 30 days of the change. [UAC R156-17b-603 (3) (s)]
4			A remote dispensing pharmacy shall display a sign easily visible to the public that informs patients of the following: that the pharmacy is a remote dispensing pharmacy; the location of the supervising pharmacy; and that at the patient's request, a pharmacist will counsel the patient using audio and video communication systems. [UAC R156-17b-614g (10) (b) (A-C)]
5			Unless a pharmacist is physically present, a remote dispensing pharmacy shall be staffed by no more than two licensed pharmacy technicians. [UAC R156-17b-614g (6) (b)]
6			At all times that a remote dispensing pharmacy is open and available to serve patients, all pharmacy technicians shall remain under the physical or electronic supervision of a supervising pharmacist from the supervising pharmacy. [UAC R156-17b-614g (6) (d)]
7			The supervising pharmacy shall maintain a telepharmacy system that provides for effective video and audio communication between supervising pharmacy personnel and remote dispensing personnel and patients, that: provides an adequate number of views of the entire site; facilitates adequate pharmacist supervision; allows the appropriate exchanges of visual, verbal, and written communication for patient counseling and other matters involved in the lawful transaction or dispensing of drugs;
			confirms that the drug selected to fill the prescription is the same as indicated on the prescription label and the prescription; and is secure and HIPAA compliant as defined in R156-17b-102(64). [UAC R156-17b-614a (7) (a-e)]
8			Adequate supervision by a supervising pharmacist of a remote dispensing pharmacy shall include maintaining uninterrupted visual supervision and auditory communication with the site, and full supervisory control of the automated system, if applicable. This supervision may not be delegated to any other person. [UAC R156-17b-614g (6) (e)]
9			Each component of the telepharmacy system shall be in good working order. If any component of the system is malfunctioning the remote dispensing pharmacy shall immediately close to the public and remain closed until system corrections or repairs are completed, unless a pharmacist is present onsite. [UAC R156-17b-614g (8)]
10			The supervising pharmacy shall develop and include in both the supervising pharmacy's and the remote dispensing pharmacy's policies and procedures a plan for continuation of services by the remote dispensing pharmacy in case of an emergency interruption: [UAC R156-17b-614g (9) (a,b)]

		The plan shall address the timely arrival at the remote dispensing pharmacy of necessary personnel, and the delivery to the remote dispensing pharmacy of necessary supplies, within a reasonable period of time following the identification of an emergency need. A supervising pharmacist shall be available onsite at the remote dispensing pharmacy as soon as possible after an emergency, and shall notify the Division in writing if the time exceeds 24 hours. The plan may provide for alternate methods of continuation of the services of the remote dispensing pharmacy, including personal delivery of patient prescriptions from an alternate pharmacy location or on-site pharmacist staffing at the remote dispensing pharmacy.
11		All individuals employed in a pharmacy facility having any contact with the public or patients receiving services from that pharmacy facility does wear on their person a clearly visible and readable identification showing the individual's name and position. [UCA 58-17b-603 (1)]
12		When communicating by any means, written, verbal, or electronic, pharmacy personnel do identify themselves as to licensure classification. [UCA 58-17b-603 (2)]
13		The facility or parent company shall maintain a record for not less than five years of the initials or identification codes that identify each dispensing pharmacist by name. The initials or identification code shall be unique to ensure that each pharmacist can be identified; therefore identical initials or identification codes shall not be used. [UAC R156-17b-614a (9)]
14		The facility does have current and retrievable editions of the following reference publications in print or electronic format and readily available and retrievable to facility personnel: UCA 58-1 (DOPL Licensing Act) UAC R156-1 (General Rules of DOPL)
		UCA 58-17b (Pharmacy Practice Act) UAC R156-17b(Pharmacy Practice Act Rules)
		UCA 58-37 (Controlled Substance Act) UAC R156-37 (Controlled Substance Act Rules) UAC R156-37f (Controlled Substance Database
		UCA 58-37f (Controlled Substance Database Act Rule)
		Act) Code of Federal Regulations FDA Approved Drug Product(Orange Book) General Drug References [UAC R156-17b-614a (4) (a-k)]
15		The facility is well lighted, ventilated, clean and sanitary. [UAC R156-17b-614a (1) (a)]
16		If transferring a drug from a manufacturer's or distributor's original container to another container, the dispensing area, shall have a sink with hot and cold culinary water separate and apart from restroom facilities. [UAC R156-17b-614a (1) (b)]
17		The facility is equipped to permit the orderly storage of prescription drugs and durable medical equipment in a manner to permit clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity of the product inventory.
		[UAC R156-17b-614a (1) (c)]
18		[UAC R156-17b-614a (1) (c)] The facility is equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary scope of practice to be conducted within that facility. [UAC R156-17b-614a (1) (d)]
18 19		The facility is equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary scope of practice to be conducted within that facility.

21	Ш	Ц	detection of entry at all times when the facility is equipped with a security system to permit detection of entry at all times when the facility is closed, and provide notice of unauthorized entry to an individual, and be equipped with a lock on any entrances to the facility where drugs are stored. [UAC R156-17b-614a (1) (f)(i-ii)(g)]
22			If the pharmacy does not store drugs in a locked cabinet and has a drop/false ceiling, the pharmacy's perimeter walls shall extend to the hard deck, or other measures shall be taken to prevent unauthorized entry into the pharmacy. [UAC R156-17b-614a (16)] $\[\]$ N/A
23			Only a licensed Utah pharmacist or authorized pharmacy personnel does have access to the pharmacy when the pharmacy is closed. [UAC R156-17b-614a (8)]
24			The temperature of the pharmacy is maintained within a range compatible with the proper storage of the drugs. [UAC R156-17b-614a (2)]
25	2 z		The temperature of the refrigerator and freezer is maintained within a range compatible with the proper storage of drugs requiring refrigeration or freezing. The pharmacy shall keep a daily written or electronic log of the temperature of the refrigerator or freezer on days of operation. The pharmacy shall retain the log for three years. [UAC R156-17b-614a (2)]
26			For the purpose of promoting therapeutic appropriateness, a pharmacist shall at the time of dispensing a prescription, or a prescription drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant conditions, situations or items, such as: [UAC R156-17b-611 (2) (a-g)]
			Inappropriate drug utilization Therapeutic duplications
			Drug-disease contraindications Drug-drug interactions
			☐ Incorrect drug dosage ☐ Incorrect duration of drug treatment
			Drug-allergy interactions Clinical abuse or misuse
27			Facility does have a counseling area to allow for confidential patient counseling. [UAC R156-17b-614a (6)]
28			Every pharmacy shall verbally offer to counsel a patient or a patient's agent in a personal face-to-face discussion regarding each prescription drug dispensed. If the patient's agent delivers the prescription in person to the pharmacist or pharmacy intern; or receives the drug in person at the time it is dispensed at the facility. [UCA 58-17b-613 (1)]
29		20	The offer to counsel is documented and said documentation shall be available to the Division. These records must be maintained for a period of five years and be available for inspection within 7-10 business days. [UAC R156-17b-610 (4)]
30			Each drug dispensed from the pharmacy does have a label securely affixed to the container indicating the required minimum information, including: [UCA 58-17b-602 (5) (a-h)]
			filling date or last dispensing date name of the patient or animal owner/species
			name of the prescriber directions for use & cautionary statements
			trade, generic or chemical name amount dispensed & strength of dosage form
			(Unless Otherwise Indicated by Prescriber)
31			Centralized prescription processing services may be performed if the parties: [UCA R156-17b-614f (1) (a-c)]
			have common ownership or common administrative control; or have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract; and share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to fill or refill a prescription order.

32		maintain a policy and procedures manual, and documentation of implementation, which shall be made available to the Division upon inspection and which includes the following: [UCA R156-17b-614f(2)(a-e)]
		a description of how the parties will comply with federal and state laws and regulations;
		appropriate records to identity the responsible pharmacists and the dispensing and counseling process;
		a mechanism for tracking the prescription drug order during each step in the dispensing process;
		a description of adequate security to protect the integrity and prevent the illegal use or disclosure of protected health information; and
		a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.
33		A copy of the proposed policies and procedures manual for the remote dispensing pharmacy and supervising pharmacy, which shall include: [UAC R156-17b-614g (4) (g) (i-vii)] protecting the confidentiality and integrity of patient information;
		the conditions under which prescription drugs shall be stored, used, and accounted for;
		maintaining records to identify the names (s), initial (s), or identification code (s) and specific activities of each pharmacist and pharmacy technician involved in the dispensing process;
		complying with federal and state law and regulations; operation of a quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems;
		annually reviewing the written policies and procedures and documenting such review;
		requiring monthly in-person inspections of the remote dispensing pharmacy and appropriate documentation by the RDPIC;
34		The remote dispensing pharmacy shall retain a recording of surveillance, excluding patient communications, for at least 45 days. [UAC R156-17b-614g (11) (b)]
35		Unless otherwise requested, child-resistant containers are used for dispensing medications to patients. [UCA 58-1-502(6) & 16 CFR 1700.14]
36		Controlled substances are not accepted back for destruction unless allowed for by state and federal law. [UAC R156-37-606 (1-2) & 21 CFR 1307.21]
37		The registered pharmacy only processes electronically signed prescriptions for controlled substances under the following conditions: the pharmacy uses a pharmacy application that meets
		all the applicable requirements; the prescription is otherwise in conformity with the requirements of the Code of Federal Regulations; and Certification Authority (CA) has been obtained. The electronic prescription must be transmitted from the practitioner to the pharmacy in its electronic form and at no time may the prescription be converted to another form (<i>i.e. facsimile</i>) for transmission. [CFR, Title 21, Chapter 11, Section 1311, UAC R156-17b-613 (1)]
38		Prescription files, including refill information, is maintained for a minimum of five years and shall be immediately retrievable in written or electronic format. [UAC R156-17b-612 (4)]
39		Electronic records shall be available to and accessible from both the remote dispensing pharmacy and the supervising pharmacy [UAC R156-17b-614g (11) (ii)]

40		including telephone prescriptions, is maintained in a physical file and contains all of the inforequired by federal and state law; and an automated data processing system is used for the sand immediate retrieval of refill information for prescription orders. [UAC R156-37-602 (4) (a-b)]	rmation
41		The original records of the controlled substance prescriptions dispensed from the remote dispensing pharmacy shall be maintained at the remote dispensing pharmacy. R156-17b-614g (11) (iii)	[UAC
42		The RDPIC shall oversee documented monthly inspections of the remote dispensing pharma Documentation of such inspections shall be kept for five years, and shall includes: R156-17b-614g (11) (c) (i-iv)]	cy. [UAC
		 ☐ maintenance and reconciliation of all controlled substances; ☐ a perpetual inventory of Schedule II controlled substances; ☐ temperature logs of the refrigerator and freezer that hold medications; and ☐ the RDPIC's periodic review of the record of entries into the remote dispensing phase 	ırmacy.
43		All records relating to Schedule II controlled substances received, purchased, administered of dispensed by the practitioner shall be maintained separately from all other records of the phor practice. Records shall be maintained by the licensee for a period of five years. [UAC R156-37-602(3, 5)]	
44		All records relating to Schedule III, IV, V controlled substances received, purchased, adminis dispensed by the practitioner shall be maintained separately from all other records of the phor practice. Records shall be maintained by the licensee for a period of five years. [UAC R156-37-602(3,6)]	
45	<i>y</i>	Requirement for annual controlled substances inventory shall be within 12 months followin inventory date of each year and may be taken within four days of the specified inventory dat shall include all stocks including out-of-date drugs and drugs in automated pharmacy system [UAC R156-17b-605 (4)]	e and
46		General Requirements for inventory of a pharmacy shall include: [UAC R156-17b-605 (2)(a)(b)(c)	(e)(f)(j)]
		the PIC shall be responsible for taking all required inventories, but may delegate the performance of the inventory to another person or persons;	
		the inventory records shall be maintained for a period of five years and be readily available inspection	for
		the inventory records shall be filed separately from all other records	
		the inventory may be taken either as the opening of the business or the close of business or inventory date;	the
		the person taking the inventory and the PIC shall indicate the time the inventory was taken shall sign and date the inventory with the date the inventory was taken. The signature of the and the date of the inventory shall be documented within 72 hours or three working days of the completed initial, annual, change of ownership and closing inventory.	PIC
		if the pharmacy maintains a perpetual inventory of any of the drugs required to be inventory the perpetual inventory shall be reconciled on the date of the inventory.	ries,
47		All pharmacies shall maintain a perpetual inventory of all Schedule II controlled substances. R156-17b-605(7)]	[UAC
48		The pharmacy does reconcile its controlled substance inventory to account for shortages of controlled substances. [UAC R156-17b-603 (3) (k) & R156-37-502(5)]	

49	225	Any facility who experiences a shortage or theft of controlled substances will immediately notify law enforcement and file the appropriate forms with the Drug Enforcement Administration, with a copy to the Division directed to the attention of the Investigation Bureau of the Division. [UAC R156-37-602 (2)]
50		Pharmacists or other responsible individuals do verify that the suppliers' invoices of controlled substances, listed on the invoices were actually received by clearly recording their initials and the actual date of receipt of the controlled substances. [UAC R156-17b-614a (12)]
51		The facility does maintain a record of suppliers' credit memos for controlled substances. [UAC R156-17b-614a (13)]
52		The facility does maintain a copy 3 of DEA order form (form 222) which has been properly dated, initialed, and filed and all copies of each unaccepted or defective order form and any attached statements or other documents. [UAC R156-17b-614a(10)]
53		The Division shall implement on a statewide basis, including non-resident pharmacies as defined in Section 58-17b-102, the following two options for a pharmacist to submit information: real-time submission of the information required to be submitted under this part of the controlled substance database; and 24-hour daily or next business day, whichever is later, batch submission of the information required to be submitted under this part to the controlled substance database. [UCA 58-37f-203(1)(a)(i,ii)]
54	, v	The PIC will for each controlled substance dispensed by a pharmacist under the PIC's supervisionsubmit to the divisionpositive identification of the individual receiving the prescription, including the type of identification and any identifying numbers on the identification. [UCA 58-37f-203 (3) (e)]
56		The pharmacy maintains automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home? If the answer is "yes", note type and location.
57		The pharmacy utilizes an Automated Pharmacy System? If the answer is "yes" to this question, a automation questionnaire must be completed. [UAC R156-17b-620]
150		COMMENTS

COMMENTS

estigator has reviewed the above nsible Party."
Date:
Date:
 Revised 11/2019